MEC
DYNAMICS

JAN 7 2013

SECTION 8
510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The assigned 510(k) number is K121752.

807.92 (a)(1): Name: MEC Dynamics Corporation
Address: 90 Rose Orchard Way
San Jose, CA 95134

Phone: (408) 428-9427
FAX: (408) 456-0279
Contact: Mr. Emmanuel Mpock

807.92 (a)(2): Device name- trade name and common name, and classification

Trade name:
Avie™ Total Hb Test System

Common Name: Total Hemoglobin Analyzing System

Classification: Total hemoglobin assay, §21 CFR 864.5620

807.92 (a)(3): Identification of the legally marketed predicate devices

HemoCue® 201+ (HemoCue AB, Sweden)

807.92 (a)(4): Device Description

The Avie™ Total Hb Test System is a point of care (POC) IVD system that utilizes general chemistry reactions to quantify total hemoglobin in fresh capillary blood and venous blood. The test system includes a small instrument (Reader) and disposable reagent strips- the strips are packaged in a reusable canister with desiccant, similar to the packaging of routine urine test strips. The concentration of total hemoglobin is calculated photometrically and is based on the optical intensity of the reaction within the quantitative area of the test strip. The calibration of the Avie™ Total Hb Test is traceable to the same high-order reference method as the HemoCue (hemiglobincyanide [HiCN].

807.92 (a)(5): Indications Use

The Avie™ Total Hb Test System is for the quantitative measurement of total hemoglobin in whole blood (capillary or venous EDTA, K2). The test system is designed for point-of-care use in primary care settings. The test system is for professional *in vitro* diagnostic use only.

807.92 (a)(6): Technological Similarities and Differences to the Predicate

The following chart describes similarities and differences between the two test systems.

Characteristic	**HemoCue® 201+ System K041234**	**Avie™ Total Hb K121752**
Sample Type	Capillary and venous whole blood	Capillary and venous EDTA, K2 whole blood
Visual Display	LCD readout	LCD readout
Test Principle	General chemistry using a modified azidemethohemoglobin reaction. Reaction takes 60 sec	Photometric measurement of total Hemoglobin concentration in sample. Final results in 15 sec
Calibration	Factory calibrated	Factory calibrated reader against HiCN method (CLSI reference method, CLSI Doc H15-A3).
Recommended Testing Environment	Doctors' offices	Doctors' offices
Reagent Storage	Room temperature	Room temperature
Operating Conditions	65-90 ° F (18-32°C), less than 85% relative humidity (without condensation).	59-113 ° F (15-45°C), less than 85% relative humidity (without condensation).
Reportable Range	0- 25.6 g/dL	5- 24.0 g/dL
Quality Control Requirements	Users are directed to perform daily electronic quality control testing and liquid control testing: with each new shipment and/or lot of test strips, or when test results are suspect	Users are directed to perform daily liquid control testing, testing of each new shipment and/or lot of test strips, or when test results are suspect

807.92 (b)(1): Brief Description of Nonclinical Data

A series of studies were performed that evaluated the following nonclinical performance characteristics: linearity, 20-day in-house precision, and interference testing,

Linearity

Eleven samples that spanned a wide range of Hb concentrations were prepared by mixing various proportions of low and high concentration samples. The samples were assayed by Avie™, and observed results were compared to expected results, based on the mathematical calculations of the proportions. The linear range of the Avie™ test system is 5 to 24 g/dL.

20-day In-house Precision

The studies followed CLSI EP5-A2, where three levels of samples were each tested four-times a day for 20 days. The results were as follows:

Precision Summary:

		Mean (g/dL)	Within-Day %CV	Total %CV
Total Hb	Level 1	7.7	2.0	2.2
n= 80 per level	Level 2	15.7	2.4	2.5
	Level 3	20.1	1.3	1.3

Interference Testing

The studies followed CLSI EP7-A2. The data demonstrated that the Avie™ Total Hb Test System was not affected by high levels of the following substances at the levels noted:

Interferent	Interferent Concentration (mg/dL)
Acetaminophen	20.0
Acetylsalicylic acid	65.2
L-Ascorbic acid	3.0
Bilirubin (unconjugated)	10.0
Creatinine	5.0
Ibuprofen	50.0
Intralipid	400
Tetracycline	1.51
Urea	257
Uric acid	23.5

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807.92 (b)(2): Brief Description of Clinical Data

Studies for precision and method comparison (accuracy) were performed at three external POL-type sites to evaluate the Avie™ Total Hb Test System in one of its targeted intended use environments, the physician's office laboratory.

Precision:

Three controls (low, mid and high Total Hb) were tested over multiple days, by multiple operators at multiple sites.

			Level 1				Level 2				Level 3			
Site #	Operators	Days	n	Mean	SD	%CV	n	Mean	SD	%CV	n	Mean	SD	%CV
Site 1	5	3	30	5.6	0.1	1.0	30	11.1	0.2	2.1	30	14.3	0.3	2.0
Site 2	6	2	30	5.3	0.0	0.8	30	10.7	0.3	2.8	30	13.7	0.2	1.4
Site 3	8	2	30	5.4	0.1	1.2	30	10.8	0.3	3.0	30	14.1	0.3	2.3

Accuracy:

Accuracy studies were conducted at three US clinical sites. A total of nine (9) Avie™ Total Hb Readers and four (4) Avie™ Total Hb Test strip lots were used for this study. Capillary and venous sampling was performed on each patient for testing on the Avie™ Total Hb System. A portion of the sampled capillary and venous blood was tested for total hemoglobin using the HiCN method for comparison. The results ranged from 5.1 to 23.5 g/dL total hemoglobin. Comparative results are shown below.

	n	Min g/dL	Max g/dL	Slope	y-intercept	"r"
Avie™ Professional Capillary vs. HiCN	177	9.5	18.0	1.02	0.13	0.97
Avie™ Venous vs. HiCN	224	5.1	23.5	1.04	-0.42	0.99

807.92 (b)(3): Conclusions from Nonclinical and Clinical Testing

Nonclinical and clinical testing was performed for the Avie Total Hb Test System. The test system was shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

JAN 7 2013

MEC Dynamics Corporation (MEC)
c/o Mr. Emmanuel Mpock
President and CEO
90 Rose Orchard Way
San Jose, California 95134

Re: k121752

Trade/Device Name: Avie™ Total Hb Test System
Regulation Number: 21 CFR §864.5620
Regulation Name: Automated hemoglobin system
Regulatory Class: II
Product Code: GKR
Dated: December 26, 2012
Received: December 28, 2012

Dear Mr. Mpock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(K) Number (if known): K121752

Device Name: Avie™ Total Hb Test System

Indications for Use:

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Prescription Use __X___ AND/OR Over the Counter Use ___
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety